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(54) Title: APPARATUS AND METHOD FOR MONITORING AND COMMUNICATING WELLNESS PARAMETERS OF AMBULATORY PATIENTS (57) Abstract The monitoring device incorporates transducing devices for converting the desired measured parameters into electrical signals capable of being processed by a local computer or microprocessor system. The device interacts with the ambulatory patient and then, via a modem or other electronic communication device, transmits the measured parameters to a computer located at a remote site. At the remote location, the various indicia of the ambulatory patient's condition are monitored and analyzed by the medical professional caregiver. To provide the ambulatory patient with an added level of convenience and ease of use, such monitoring device is contained in a single integrated package.		

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**APPARATUS AND METHOD FOR
MONITORING AND COMMUNICATING
WELLNESS PARAMETERS OF AMBULATORY
PATIENTS**

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Background

There is a need in the medical profession for an apparatus and method capable of monitoring and transmitting physiological and wellness parameters of ambulatory patients to a remote site where a medical professional caregiver evaluates such physiological and wellness parameters. Specifically, there is a need for an interactive apparatus that is coupled to a remote computer such that a medical professional caregiver can supervise and provide medical treatment to remotely located ambulatory patients.

There is needed an apparatus that monitors and transmits physiological and wellness parameters of ambulatory patients to a remote computer, whereby a medical professional caregiver evaluates the information and provokes better overall health care and treatment for the patient. Accordingly, such an apparatus can be used to prevent unnecessary hospitalizations of such ambulatory patients.

Also, there is needed an apparatus for monitoring and transmitting such physiological and wellness parameters that is easy to use and that is integrated into a single unit. For example, there is a need for an ambulatory patient monitoring apparatus that comprises: a transducing device for providing electronic signals representative of measured physiological parameters, such as weight; an input/output device; and a communication device as a single integrated unit that offers ambulatory patients ease of use, convenience and portability.

Patients suffering from chronic diseases, such as chronic heart failure, will benefit from such home monitoring apparatus. These patients normally undergo drug therapy and lifestyle changes to manage their medical condition. In these patients, the medical professional caregiver monitors certain wellness parameters and symptoms including: weakness, fatigue, weight gain, edema, dyspnea (difficulty breathing or shortness of breath), nocturnal cough, orthopnea (inability to lie flat in bed because of shortness of breath), and paroxysmal nocturnal dyspnea (awakening short of breath relieved by sitting or standing); and body weight to measure the response of drug therapy. Patients will also benefit from daily reminders to take medications (improving compliance), reduce sodium intake and perform some type of exercise. With the information received from the monitoring device, the medical professional caregiver can determine the effectiveness of the drug therapy, the

patient's condition, whether the patient's condition is improving or whether the patient requires hospitalization or an office consultation to prevent the condition from getting worse.

Accordingly, there is needed an apparatus and method for monitoring the patients from a remote location, thus allowing medical professional caregivers to receive feedback of the patient's condition without having to wait until the patient's next office visit. In addition, there is needed an apparatus and method that allows medical professional caregivers to monitor and manage the patient's condition to prevent the rehospitalization of such patient, or prevent the patient's condition from deteriorating to the point where hospitalization would be required. As such, there are social as well as economic benefits to such an apparatus and method.

The patient receives the benefits of improved health when the professional caregiver is able to monitor and quickly react to any adverse medical conditions of the patient or to any improper responses to medication. Also, society benefits because hospital resources will not be utilized unnecessarily.

As a group, patients suffering from chronic heart failure are the most costly to treat. There are approximately 5 million patients in the U.S.A. and 15 million worldwide with chronic heart failure. The mortality rate of patients over 65 years of age is 50%. Of those that seek medical help and are hospitalized, 50% are rehospitalized within 6 months. Of these, 16% will be rehospitalized twice. The patients that are hospitalized spend an average of 9.1 days in the hospital at a cost of \$12,000.00 for the period. Accordingly, there is a need to reduce the rehospitalization rate of chronic heart failure patients by providing improved in-home patient monitoring, such as frequently monitoring the patient's body weight and adjusting the drug therapy accordingly.

Approximately 60 million American adults ages 20 through 74 are overweight. Obesity is a known risk factor for heart disease, high blood pressure, diabetes, gallbladder disease, arthritis, breathing problems, and some forms of cancer such as breast and colon cancer. Americans spend \$33 billion dollars annually on weight-reduction products and services, including diet foods, products and programs.

There is a need in the weight management profession for an apparatus and method capable of monitoring and transmitting physiological and wellness parameters of overweight/obese patients to a remote site where a weight management professional or nutritionist evaluates such physiological and wellness

parameters. Specifically, there is a need for an interactive apparatus that is coupled to a remote computer such that a weight management professional or nutritionist can supervise and provide nutritional guidance to remotely located individuals.

The apparatus allows overweight individuals to participate in a weight loss/management program with accurate weight monitoring from home. The apparatus improves the convenience for the individual participant by eliminating the need to constantly commute to the weight management center and "weigh-in." Furthermore, the individual can participate in a weight management program while under professional supervision from the privacy and comfort of their own home. Moreover, the apparatus allows the weight management professional to intervene and adapt the individuals diet and exercise routine based on the weight and wellness information received.

For the foregoing reasons, there is a need for an apparatus, system and method capable of monitoring and transmitting physiological and wellness parameters of ambulatory patients, such as body weight, to a remote location where a medical professional caregiver, weight management professional or nutritionist can evaluate and respond to the patient's medical wellness condition.

Summary

The invention is directed to an apparatus, system and method that satisfies this need. The apparatus having features of the invention is capable of monitoring an ambulatory patient and establishing two way communication to a medical professional caregiver, weight management professional or nutritionist regarding the wellness parameters of such an ambulatory patient.

The apparatus comprises a physiological parameter transducing device. The device generates an electronic signal that is representative of the value of the physiological parameter being monitored. The apparatus further comprises a central processor device. The central processor device is operatively coupled to the parameter transducing device and processes the electronic signals that are representative of the physiological parameters. The apparatus further comprises an electronic receiver/transmitter communication device. The communication device having one end operatively coupled to the processor and another end operatively coupled to a communication network. The communication device is activated whenever the central processor recognizes a physiological parameter within a predetermined range. The apparatus further comprises an input device. The input

device is operatively coupled to said processor and configured to receive external commands. The apparatus further comprises an output device. The output device is coupled to the processor and provides information comprising external commands, physiological symptoms, wellness parameters, and queries from the communication device. All of these devices are integrated into a single unit.

The system having features of the invention monitors an ambulatory patient and establishes communication to a caregiver, regarding the wellness parameters of such an ambulatory patient, between a first location and a remote central office location. The system comprises a monitoring apparatus located at the first location.

10 The monitoring apparatus comprises: (a) a physiological parameter transducing device that generates an electronic signal representative of the value of the physiological parameter being monitored; (b) a central processor device that is operatively coupled to the parameter transducing device for processing the physiological parameter electronic signals; (c) an electronic receiver/transmitter

15 communication device, said communication device having one end operatively coupled to the processor and another end operatively coupled to a communication network that is activated whenever the central processor recognizes a physiological parameter within a predetermined range; (d) an input device that is operatively coupled to the processor and configured to receive external commands; (e) an output

20 device coupled to the processor that provides information comprising external commands, physiological symptoms, wellness parameters, and queries from the communication device, wherein these devices are integrated into a single unit. The system further comprises a processing computer at a remote central office location that is in communication with the remote monitoring apparatus and exchanges

25 information with the monitoring apparatus.

The method having features of the invention monitors an ambulatory patient and establishes communication to a caregiver regarding the wellness parameters of such an ambulatory patient. The method comprises monitoring a physiological parameter; generating an electronic signal representative of the value of the

30 physiological parameter; in a central processor device, processing the physiological parameter electronic signals; communicating the processed electronic signals between a first location and a remote central location; inputting external commands into the processor; and outputting the information.

Brief Description of the Drawings

These and other features, aspects and advantages of the invention will become better understood with regard to the following description, appended claims and accompanying drawings where:

5 Figs. 1A-E illustrates several embodiments of the monitoring apparatus in accordance with the invention;

Fig. 2 illustrates a monitoring apparatus with a support member in accordance with one embodiment of the invention;

10 Fig. 3 illustrates a monitoring apparatus with a support member in accordance with one embodiment of the invention;

Fig. 4 is a functional block diagram of a microprocessor system forming an environment in which one embodiment of the invention may be employed;

Fig. 5 is functional block diagram of a microprocessor system forming the environment in which one embodiment of the invention may be employed;

15 Fig. 6 is a functional block diagram of a microprocessor system forming the environment in which one embodiment of the invention may be employed;

Fig. 7 illustrates a system in which one embodiment of the invention may be employed;

20 Fig. 8 is a logic flow diagram illustrating the steps utilized to implement one embodiment of the invention;

Fig. 9 illustrates a sectional view of the electronic scale in accordance with one embodiment of the invention; and

Fig. 10 illustrates a top plate of the electronic scale in accordance with one embodiment of the invention.

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Description

The embodiments of the invention described herein are implemented as a medical apparatus, system and method capable of monitoring wellness parameters and physiological data of ambulatory patients and transmitting such parameters and data to a remote location. At the remote location a medical professional caregiver monitors the patient's condition and provides medical treatment as may be necessary.

30 The monitoring device incorporates transducing devices for converting the desired measured parameters into electrical signals capable of being processed by a local computer or microprocessor system. The device interacts with the ambulatory patient and then, via an electronic communication device such as a modem,

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transmits the measured parameters to a computer located at a remote site. At the remote location the various indicia of the ambulatory patient's condition are monitored and analyzed by the medical professional caregiver. To provide the ambulatory patient with an added level of convenience and ease of use, such monitoring device is contained in a single integrated package.

Communication is established between the monitoring apparatus and a remote computer via modem and other electronic communication devices that are generally well known commercially available products. At the remote location, the caregiver reviews the patient's condition based on the information communicated (e.g. wellness parameters and physiological data) and provokes medical treatment in accordance with such information.

Referring now to Fig. 1A, as this embodiment of the invention is described herein, an integrated monitoring apparatus is shown generally at 10. The integrated monitoring apparatus 10 includes an electronic scale 18. The electronic scale 18 further includes a top plate 11 and a base plate 12. The integrated monitoring apparatus 10 further includes a housing 14 and a support member 16A. The base plate 12 is connected to the housing 14 through the support member 16A. The housing 14 further includes output device(s) 30 and input device(s) 28. The apparatus 10 is integrated as a single unit with the support member coupling the base plate 12 and the housing 14, thus providing a unit in a one piece construction.

It will be appreciated that other physiological transducing devices can be utilized in addition to the electronic scale 18. For example, blood pressure measurement apparatus and electrocardiogram (EKG) measurement apparatus can be utilized with the integrated monitoring apparatus 10 for recordation and/or transmission of blood pressure and EKG measurements to a remote location. It will be appreciated that other monitoring devices of physiological body functions that provide an analog or digital electronic output may be utilized with the monitoring apparatus 10.

Referring to Figs. 1B, 1C, 1D and 1E it will be appreciated that the support member 16A (Fig. 1A) can be made adjustable. For example, Fig. 1B illustrates an embodiment of the invention utilizing a telescoping support member 16B. Likewise, Fig. 1C illustrates an embodiment of the invention utilizing a folding articulated support member 16C. Fig. 1D illustrates yet another embodiment of the invention utilizing support member 16D that folds at a pivot point 25 located at its base. It will also be appreciated that other types of articulated and folding support members

may be utilized in other embodiments of the invention. For example, Fig. 1E illustrates an embodiment of the invention providing a support member 16E that is removably insertable into a socket 23. A cable 22 is passed through the support member 16E to carry electrical signals from the electronic scale 18 to the housing 14 for further processing. A tether 20 is provided to restrain the movement of the support member 16E relative to the base plate 12 once the it is removed from the socket 23.

Fig. 2 illustrates an embodiment of the invention where the support member 82 folds about pivot point 84. Folding the integrated monitoring apparatus about pivot point 84 provides a convenient method of shipping, transporting or moving the apparatus in a substantially horizontal orientation. The preferred direction of folding is indicated in the figure, however, the support member 82 can be made to fold in either direction. Furthermore, an embodiment of the invention provides rubber feet 85 underneath the base plate 12.

Furthermore, Fig. 3 illustrates one embodiment of the invention providing an articulated, folding support member 86. The support member 86 folds at two hinged pivot points 88, 90. Also illustrated is a sectional view of the scale 18, top plate 11, base plate 12, load cell 100 and strain gage 102.

Referring now to Fig. 4, a microprocessor system 24 including a CPU 38, a memory 40, an optional input/output (I/O) controller 42 and a bus controller 44 is illustrated. It will be appreciated that the microprocessor system 24 is available in a wide variety of configurations and is based on CPU chips such as the Intel, Motorola or Microchip PIC family of microprocessors or microcontrollers.

It will be appreciated by those skilled in the art that the monitoring apparatus requires an electrical power source 19 to operate. As such, the monitoring apparatus may be powered by: ordinary household A/C line power, DC batteries or rechargeable batteries. Power source 19 provides electrical power to the housing for operating the electronic devices. A power source for operating the electronic scale 18 is generated within the housing, however those skilled in the art will recognize that a separate power supply may be provided or the power source 19 may be adapted to provide the proper voltage or current for operating the electronic scale 18.

The housing 14 includes a microprocessor system 24, an electronic receiver/transmitter communication device such as a modem 36, an input device 28 and an output device 30. The modem 36 is operatively coupled to the microprocessor system 24 via the electronic bus 46, and to a remote computer 32 via

a communication network 34 and modem 35. The communication network 34 being any communication network such as the telephone network, wide area network or Internet. It will be appreciated that the modem 36 is a generally well known commercially available product available in a variety of configurations operating at a variety of BAUD rates. In one embodiment of the invention the modem 36 is asynchronous, operates at 2400 BAUD and is readily available off-the-shelf from companies such as Rockwell or Silicon Systems Inc. (SSI).

It will be appreciated that output device(s) 30 may be interfaced with the microprocessor system 24. These output devices 30 include a visual electronic display device 31 and/or a synthetic speech device 33. Electronic display devices 31 are well known in the art and are available in a variety of technologies such as vacuum fluorescent, liquid crystal or Light Emitting Diode (LED). The patient reads alphanumeric data as it scrolls on the electronic display device 31. Output devices 30 include a synthetic speech output device 33 such as a Chipcorder manufactured by ISD (part No. 4003). Still, other output devices 30 include pacemaker data input devices, drug infusion pumps or transformer coupled transmitters.

It will be appreciated that input device(s) 28 may be interfaced with the microprocessor system 24. In one embodiment of the invention an electronic keypad 29 is provided for the patient to enter responses into the monitoring apparatus. Patient data entered through the electronic keypad 29 may be scrolled on the electronic display 31 or played back on the synthetic speech device 33.

The microprocessor system 24 is operatively coupled to the modem 36, the input device(s) 28 and the output device(s) 30. The electronic scale 18 is operatively coupled to the central system 24. Electronic measurement signals from the electronic scale 18 are processed by the A/D converter 15. This digitized representation of the measured signal is then interfaced to the CPU 38 via the electronic bus 46 and the bus controller 44. In one embodiment of the invention, the physiological transducing device includes the electronic scale 18. The electronic scale 18 is generally well known and commercially available. The electronic scale 18 may include one or more of the following elements: load cells, pressure transducers, linear variable differential transformers(LVDTs), capacitance coupled sensors, strain gages and semiconductor strain gages. These devices convert the patient's weight into a useable electronic signal that is representative of the patient's weight.

It will be appreciated that Analog-to-Digital (A/D) converters are also generally well known and commercially available in a variety of configurations. Furthermore, an A/D converter 15 may be included within the physiological transducing device or within the microprocessor system 24 or within the housing 14.

- 5 One skilled in the art would have a variety of design choices in interfacing a transducing device comprising an electronic sensor or transducer with the microprocessor system 24.

The scale 18 may provide an analog or digital electronic signal output depending on the particular type chosen. If the electronic scale 18 provides an
10 analog output signal in response to a weight input, the analog signal is converted to a digital signal via the A/D converter 15. The digital signal is then interfaced with the electronic bus 46 and the CPU 38. If the electronic scale 18 provides a digital output signal in response to a weight input, the digital signal may be interfaced with electronic bus 46 and the CPU 38.

- 15 Fig. 5 illustrates one embodiment of the invention where the communication device is a radio frequency (RF) transceiver. The transceiver comprises a first radio frequency device 50 including an antenna 52, and a second radio frequency device 54, including an antenna 56. The first radio frequency device 52 is operatively coupled to the microprocessor system 24 via the electronic bus 46, and is in radio
20 communication with the second radio frequency device 54. The second radio frequency device 54 is operatively coupled through a microprocessor 55 which is operatively coupled to a modem 58. The modem 58 is coupled to the communication network 34 and is in communication with the remote computer 32 via the modem 35. The first radio frequency device 50 and the second radio
25 frequency device 54 are remotely located, one from the other. It will be appreciated that such radio frequency devices 50, 54 are generally well known and are commercially available products from RF Monolithics Inc. (RFM).

- In one embodiment of the invention, such transceivers operate at radio frequencies in the range of 900-2400 MHz. Information from the microprocessor
30 system 24 is encoded and modulated by the first RF device 50 for subsequent transmission to the second RF device 54, located remotely therefrom. The second RF device 54 is coupled to a conventional modem 58 via the microprocessor 55. The modem 58 is coupled to the communication network 34 via a in-house wiring connection and ultimately to the modem 35 coupled to the remote computer 32.
35 Accordingly, information may be transmitted to and from the microprocessor system

24 via the RF devices 50, 54 via a radio wave or radio frequency link, thus providing added portability and flexibility to the monitoring apparatus 10. It will be appreciated that various other communications devices may be utilized such as RS-232 serial communication connections, Internet communications connection as well
5 as satellite communication connections. Other communications devices that operate by transmitting and receiving infra-red (IR) energy can be utilized to provide a wireless communication link between the patient monitoring apparatus 10 and a conveniently located network connection. Furthermore, X-10™ type devices can also be used as part of a communication link between the patient monitoring
10 apparatus 10 and a convenient network connection in the home. X-10 USA and other companies manufacture a variety of devices that transmit/receive data without the need for any special wiring. The devices works by sending signals through the home's regular electrical wires using what is called power line carrier (PLC).

Referring now to Fig. 6, one embodiment of the invention wherein a digital
15 electronic scale 21 is provided. Digital weight measurements from the digital electronic scale 21 may be interfaced with the microprocessor system and CPU 38 without requiring additional amplification, signal conditioning and A/D converters.

Referring now to Fig. 7, a two way communication system in accordance with the principals of the present invention is shown. The physiological data of an
20 ambulatory patient is monitored utilizing monitoring apparatus 10 at a local site 58 and is transmitted to a remote computer 32 located at a remote computer site 62 via communication network 34. At the remote computer site 62 a medical professional caregiver such as a nurse, physician or nurse practitioner monitors the patient data and provokes treatment in accordance with such data.

25 Operations to perform the preferred embodiment of the invention are shown in Fig. 8. Block 64 illustrates the operation of monitoring or measuring the ambulatory patient's physiological parameter. In one embodiment of the invention, namely for chronic heart failure patients, the physiological parameter monitored is the patient's weight. However, it will be appreciated by those skilled in the art that
30 the physiological parameters may include blood pressure, EKG, temperature, urine output and any other.

Block 66 illustrates the operation of converting a monitored or measured physiological parameter from a mechanical input to an electronic output by utilizing a transducing device. In one embodiment of the invention the transducing device is

an electronic scale 18, which converts the patient's weight into a useable electronic signal.

At block 68, the microprocessor system 24 processes the electronic signal representative of the transduced physiological parameter. If the resulting parameter value is within certain preprogrammed limits the microprocessor system 24 initiates communication within the remote computer 32 via the communication device 36 over the communication network 34.

Block 70 illustrates the operation whereby information such as wellness parameters and physiological data are communicated between the monitoring apparatus 10 and the ambulatory patient. An exemplary list of the questions asked to the patient by the monitoring apparatus are provided in Table 5.

Referring now to Figs. 7 and 8, upon establishing communication between the local monitoring apparatus 10, at the local site 58, and the remote computer 32, at remote site 62, block 72 illustrates the operation of communicating or transmitting processed signals representative of physiological data and wellness parameters from the local site 58 to the remote site 62.

Fig. 9 is a sectional view the scale 18 portion of one embodiment of the invention. The scale 18 comprises a top plate 11 and a base plate 12. The top plate 11 and the base plate 12 having a thickness "T". A load cell 100 is disposed between the top plate 11 and the base plate 12 and rests on support/mounting surfaces 96 and 98.

The load cell 100 is a transducer that responds to a forces applied to it. During operation, when a patient steps on the electronic scale 18, the load cell 100 responds to a force "F" transmitted through the top plate 11 and a first support/mounting surface 96. The support/mounting surface 96 is contact with a first end on a top side of the load cell 100. A force "F" that is equal and opposite to "F" is transmitted from the surface that the electronic scale 18 is resting on, thorough the base plate 12 and a second support/mounting surface 98. The second support/mounting surface 98 is in contact with a second end on a bottom side of the load cell 100. In one embodiment, the load cell 100 is attached to the top plate 11 and the base plate 12, respectively, with bolts that engage threaded holes provided in the load cell 100. In one embodiment the load cell 100 further comprises a strain gage 102.

The strain gage 102 made from ultra-thin heat-treated metallic foils. The strain gage 102 changes electrical resistance when it is stressed, e.g. placed in

tension or compression. The strain gage 102 is mounted or cemented to the load cell 100 using generally known techniques in the art, for example with specially formulated adhesives, urethanes, epoxies or rubber latex. The positioning of the strain gage 102 will generally have some measurable effect on overall performance of the load cell 100. Furthermore, it will be appreciated by those skilled in the art that additional reference strain gages may be disposed on the load cell where they will not be subjected to stresses or loads for purposes of temperature compensating the strain gage 102 under load. During operation over varying ambient temperatures, signals from the reference strain gages may be added or subtracted to the measurement signal of the strain gage 102 under load to compensate for any adverse effects of ambient temperature on the accuracy of the strain gage 102.

The forces, "F" and "F'", apply stress to the surface on which the strain gage 102 is attached. The weight of the patient applies a load on the top plate 11. Under the load the strain gage(s) 102 mounted to the top of the load cell 100 will be in tension/compression as the load cell bends. As the strain gage 102 is stretched or compressed its resistance changes proportionally to the applied load. The strain gage 102 is electrically connected such that when an input voltage or current is applied to the strain gage 102, an output current or voltage signal is generated which is proportional to the force applied to the load cell 100. This output signal is then converted to a digital signal by A/D converter 15.

The design of the load cell 100 having a first end on a top side attached to the top plate 11 and a second end on a bottom side attached to the base plate 12 provides a structure for stressing the strain gage 102 in a repeatable manner. The structure enables a more accurate and repeatable weight measurement. This weight measurement is repeatable whether the scale 18 rests on a rigid tile floor or on a carpeted floor. Fig. 10 illustrates one embodiment of the top plate 11 that provides four mounting holes 106 for attaching the base plate 12 to one end of the load cell 100. The base plate 12 provides similar holes for attaching to the other end of the load cell 100. The top plate 11 and the base plate 12 (not shown) each comprise a plurality of stiffening ribs 108 that add strength and rigidity to the electronic scale 18.

Table 1 shows multiple comparative weight measurements taken with the electronic scale 18 resting on a tile floor and a carpeted floor without rubber feet on the scale 18. The measurements were taken using the same load cell 100. The thickness "T" of the top plate 11 and supporting ribs was 0.125" except around the

load cell, where the thickness of the supporting ribs was 0.250". The thickness of the load cell 100 support/mounting surfaces 96, 98 (Fig. 9) was 0.375". As indicated in Table 1, with the scale 18 resting on a tile floor, the average measured weight was 146.77 lbs., with a standard deviation of 0.11595. Subsequently, with the scale 18 resting on a 0.5" carpet with 0.38" pad underneath and an additional 0.5" rug on top of the carpet, the average measured weight was 146.72 lbs., with a standard deviation of 0.16866.

Table 1

Thick Scale Parts Around Load Cell 0.250"	
TILE (lbs.)	CARPET (lbs.)
146.9	146.7
146.7	147
146.9	146.6
146.8	146.7
146.6	146.6
146.8	147
146.8	146.5
146.7	146.6
146.9	146.8
146.6	146.7
0.11595 (stddev)	0.16866 (stddev)
146.77 (average)	146.72 (average)

Table 2 shows multiple weight measurements taken with the scale 18 on a tile floor and a carpeted floor with rubber feet on the bottom of the scale 18. The measurements were taken using the same load cell 100. The thickness "T" of the top plate 11 was 0.125" including the thickness around the load cell. As indicated in Table 2, with the scale 18 resting on a tile floor on rubber feet, the average measured weight was 146.62 lbs., with a standard deviation of 0.07888. Subsequently, with the scale 18 resting on a 0.5" carpet with 0.38" pad underneath and an additional 0.5" rug on top of the carpet, the average measured weight was 146.62 lbs., with a standard deviation of 0.04216.

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Table 2

Thin Scale Parts Throughout 0.125"	
TILE (lbs.)	CARPET (lbs.)
146.7	146.7
146.7	146.7
146.6	146.6
146.6	146.6
146.6	146.6
146.6	146.6
146.6	146.6
146.5	146.6
146.7	146.6
146.5	146.6
146.7	146.6
0.07888 (stddev)	0.04216 (stddev)
146.62 (average)	146.62 (average)

Table 3 shows multiple weight measurements taken with an off-the-shelf conventional electronic scale. As indicated in table 3, with the off-the-shelf conventional scale resting on the tile floor, the average measured weight was 165.5571 lbs., with a standard deviation of 0.20702. Subsequently, with the off-the-shelf conventional scale resting on a 0.5" carpet with 0.38" pad underneath and an additional 0.5" rug on top of the carpet, the average measured weight was 163.5143 lbs., with a standard deviation of 0.13093.

Table 3

Off-The-Shelf Conventional Scale	
TILE (lbs.)	CARPET (lbs.)
165.9	163.5
165.5	163.4
165.8	163.7
165.4	163.6
165.5	163.6
165.4	163.5
165.4	163.3
-----	163.4
0.20702 (stddev)	0.13093 (stddev)
165.5571 (average)	163.5143 (average)
2.042857 (% of difference)	1.249345 (% of difference)

The summary in Table 4 is a comparative illustration of the relative repeatability of each scale while resting either on a tile floor or on a carpeted floor.

Table 4

SUMMARY OF DATA:					
Heavy Scale Parts All 0.125" Except Cell Around the Load Cell 0.250"					
TRIAL	TILE	STDDEV	CARPET	STDDEV	TILE VS. CARPET
1	146.77	0.1159	146.72	0.1686	0.05
2	146.67	0.0823	146.72	0.1906	0.05
Thin Scale Parts All 0.125"					
1	146.62	0.0788	146.62	0.04216	0.00
Off-The-Shelf Conventional Scale					
1	165.55	0.207	163.51	0.1309	2.04

The foregoing description was intended to provide a general description of the overall structure of several embodiments of the invention, along with a brief discussion of the specific components of these embodiments of the invention. In operating the apparatus 10, an ambulatory patient utilizes the monitoring apparatus 10 to obtain a measurement of a particular physiological parameter. For example, an ambulatory patient suffering from chronic heart failure will generally be required to monitor his or her weight as part of in-home patient managing system. Accordingly, the patient measures his or her weight by stepping onto the electronic scale 18, integrally located within the base plate 12 of the monitoring apparatus 10.

Referring now to Fig. 4, the modem 36 of the monitoring apparatus 10 will only activate if the measured weight is within a defined range such as ± 10 lbs, $\pm 10\%$ or any selected predetermined value of a previous weight measurement. The patient's previous symptom free weight (dry weight) is stored in the memory 40. The dry weight is the patient's weight whenever diuretics are properly adjusted for the patient, for example. This prevents false activation of the modem 36 if a child, pet, or other person accidentally steps onto the electronic scale 18.

Upon measuring the weight, the microprocessor system 24 determines whether it is within a defined, required range such as ± 10 lbs. or $\pm 10\%$ of a previously recorded weight stored in memory 40. The monitoring apparatus 10 then initiates a call via the modem 36 to the remote site 62. Communications is established between the local monitoring apparatus 10 and the remote computer 32. In one embodiment of the invention, the patient's weight is electronically transferred from the monitoring apparatus 10 at the local site 58 to the remote computer 32 at the remote site 62. At the remote site 62 the computer program compares the patient's weight with the dry weight and wellness information and updates various

user screens. The program can also analyze the patient's weight trend over the previous 1–21 days. If significant symptoms and/or excessive weight changes are reported, the system alerts the medical care provider who may provoke a change to the patient's medication dosage, or establish further communication with the patient such as placing a telephone to the patient. The communication between the patient's location and the remote location may be one way or two way communication depending on the particular situation.

To establish the patient's overall condition, the patient is prompted via the output device(s) 30 to answer questions regarding various wellness parameters. An exemplary list of questions, symptoms monitored and the related numerical score is provided in Table 5 as follows:

TABLE 5

Health Check Score		
Question	Symptom	Value
Above Dry Weight?	Fluid accumulation	10
Are you feeling short of breath?	Dyspnea	10
Did you awaken during the night short of breath?	Paroxysmal nocturnal dyspnea	5
Did you need extra pillows last night?	Congestion in the lungs	5
Are you coughing more than usual?	Congestion in the lungs	3
Are your ankles or feet swollen?	Pedal edema	5
Does your stomach feel bloated?	Stomach edema	3
Do you feel dizzy or lightheaded?	Hypotension	5
Are you more tired than usual?	Fatigue	2
Are you taking your medication?	Medication compliance	7
Has your appetite decreased?	Appetite	2
Are you reducing your salt intake?	Sodium intake	1
Did you exercise today?	Fitness	1

At the remote site 62 the medical professional caregiver evaluates the overall score according to the wellness parameter interrogation responses (as shown in Table 5). For example, if the patient's total score is equal to or greater than 10, an exception is issued and will either prompt an intervention by the medical professional caregiver in administering medication, or prompt taking further action in the medical care of the patient.

The output device(s) 30 varies based on the embodiment of the invention. For example, the output device may be a synthetic speech generator 33. As such, the wellness parameters are communicated to the patient via the electronic synthetic speech generator 33 in the form of audible speech. It will be appreciated that

electronic speech synthesizers are generally well known and widely available. The speech synthesizer converts electronic data to an understandable audible speech.

Accordingly, the patient responds by entering either "YES" or "NO" responses into the input device 28, which may include for example, an electronic keypad 29. However, in one embodiment of the invention, the input device may also include a generic speech recognition device such as those made by International Business Machines (IBM), Dragon Systems, Inc. and other providers. Accordingly, the patient replies to the interrogations merely by speaking either "YES" or "NO" responses into the speech recognition input device.

In embodiments of the invention that include electronic display 31 as an output device 30, the interrogations as well as the responses are displayed and/or scrolled across the display for the patient to read. Generally, the electronic display will be positioned such that it is viewable by the patient during the information exchanging process between the patient and the remote computer 32.

Upon uploading the information to the remote computer 32, the medical professional caregiver may telephone the patient to discuss, clarify or validate any particular wellness parameter or physiological data point. Furthermore, the medical professional caregiver may update the list of wellness parameter questions listed in Table 5 from the remote site 62 over the two way communication network 34.

Modifications are transmitted from the remote computer 32 via modem 35, over the communication network 34, through modem 36 and to the monitoring apparatus 10. The modified query list is then stored in the memory 40 of the microprocessor system 24.

Thus, it will be appreciated that the previously described versions of invention provide many advantages, including addressing the needs in the medical profession for an apparatus and method capable of monitoring and transmitting physiological and wellness parameters of ambulatory patients to a remote site whereby a medical professional caregiver can evaluate such physiological and wellness parameters and make decisions regarding the patient's treatment.

Also, it will be appreciated that the previously described versions of invention provide other advantages, including addressing the need for an apparatus for monitoring and transmitting such physiological and wellness parameters that is available in an easy to use portable integrated single unit.

Also, it will be appreciated that the previously described versions of the invention provide still other advantages, including addressing the need for medical

professional caregivers to monitor and manage the patient's condition to prevent the rehospitalization of the patient, and to prevent the patient's condition from deteriorating to the point where hospitalization may be required.

- Although the invention has been described in considerable detail with
5 reference to certain preferred versions thereof, other versions are possible. For example a weight management and control apparatus.
Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

The Claimed Invention Is:

- 1 1. An apparatus for monitoring an ambulatory patient and establishing
2 communication to a caregiver regarding the wellness parameters of such an
3 ambulatory patient, said apparatus comprising:
4 a physiological parameter transducing device, said device generating an
5 electronic signal representative of the value of the physiological parameter being
6 monitored;
7 a central processor device, said central processor operatively coupled to said
8 parameter transducing device and processing said physiological parameter electronic
9 signals;
10 an electronic receiver/transmitter communication device, said
11 communication device having one end operatively coupled to said processor and
12 another end operatively coupled to a communication network, said communication
13 device being activated whenever the central processor recognizes a physiological
14 parameter within a predetermined range;
15 an input device, said input device operatively coupled to said processor and
16 configured to receive external commands;
17 an output device, said output device coupled to said processor and providing
18 information comprising external commands, physiological symptoms, wellness
19 parameters, and queries from said communication device;
20 wherein said devices are integrated into a single unit.
- 1 2. The apparatus according to claim 1 wherein said integrated unit comprises:
2 a base, said base including said physiological parameter transducing device;
3 a housing, said housing including said central processor device, said
4 electronic receiver/transmitter communication device, said input device and said
5 output device; and
6 a support member, said support member having a first end connected to said
7 base and a second end connected to said housing.
- 1 3. The apparatus according to claim 2, wherein said support member is rigid.
- 1 4. The apparatus according to claim 2, wherein said support member is
2 adjustable.

1 5. The apparatus according to claim 2, wherein said support member is flexible.

1 6. The apparatus according to claim 1 wherein the physiological parameter
2 transducing device is a scale for monitoring the body weight of a chronic heart
3 failure patient.

1 7. The apparatus according to claim 6 wherein said scale comprises:
2 a top plate defining an interior and exterior surface;
3 a base plate defining an interior and exterior surface;
4 a load cell having a top and bottom side and a first and second end disposed
5 between said top plate and said base plate, wherein the top side of the first end of
6 said load cell is in contact with a first support surface within the interior surface of
7 said top plate, and the bottom side of the second end of said load cell is in contact
8 with a second support surface within the interior surface of said base plate.

1 8. The apparatus according to claim 7 wherein said load cell further comprises a
2 strain gage disposed on said load cell.

1 9. The apparatus according to claim 6 further comprising means for determining
2 whether said patient requires hospitalization or medication adjustments based on
3 said body weight.

1 10. The apparatus according to claim 6 wherein the scale is accurately operable
2 on a hard floor as well as a carpeted floor.

1 11. The apparatus according to claim 1 wherein the physiological parameter
2 transducing device is a scale for monitoring the body weight of an overweight or
3 obese individual.

1 12. The apparatus according to claim 11 further comprising means for
2 determining whether said individual requires diet modification, or additional
3 nutritional consultation.

1 13. The apparatus according to claim 1 further comprising means for determining
2 whether said patient requires hospitalization or medication adjustments based on
3 said wellness parameters.

1 14. The apparatus according to claim 1, wherein said communication device is a
2 modem.

1 15. The apparatus according to claim 1, wherein said communication device is
2 an RS-232 device.

1 16. The apparatus according to claim 1, wherein said communication device is
2 an Internet communication device.

1 17. The apparatus according to claim 1, wherein said communication device is a
2 satellite communication device.

1 18. The apparatus according to claim 1, wherein said communication device is
2 an infra-red communication device.

1 19. The apparatus according to claim 1, wherein said communication device is a
2 power line carrier communication device.

1 20. The apparatus according to claim 1, wherein said communication device is a
2 Radio Frequency (RF) transceiver.

1 21. The apparatus according to claim 20, wherein said RF transceiver has first
2 and second portions, said first portion being operatively coupled to said processor
3 and in radio communication with said second portion, said second portion being
4 located remotely from said first portion and operatively coupled to said
5 communication network.

1 22. The apparatus according to claim 21, wherein said second portion includes
2 means for wall mounting said second portion.

1 23. The apparatus according to claim 1 wherein a nurse is in communication
2 with said patient through said communication network.

1 24. The apparatus according to claim 1 wherein said output device is a synthetic
2 speech communication device, said speech communication device operatively
3 coupled to said processor and audibly communicating information to said patient.

1 25. The apparatus according to claim 1 wherein said output device is a visual
2 display device.

1 26. The apparatus according to claim 1 wherein said output device is a
2 pacemaker coupled to said data input device.

1 27. A system for monitoring an ambulatory patient and establishing
2 communication to a caregiver regarding the wellness parameters of such an
3 ambulatory patient between a first location and a remote central office location, said
4 system comprising:

5 a monitoring apparatus at said first location comprising:

6 (a) a physiological parameter transducing device, said device
7 generating an electronic signal representative of the value of the physiological
8 parameter being monitored;

9 (b) a central processor device, said central processor operatively
10 coupled to said parameter transducing device and processing said physiological
11 parameter electronic signals;

12 (c) an electronic receiver/transmitter communication device, said
13 communication device having one end operatively coupled to said processor and
14 another end operatively coupled to a communication network, said communication
15 device being activated whenever the central processor recognizes a physiological
16 parameter within a predetermined range;

17 (d) an input device, said input device operatively coupled to said
18 processor and configured to receive external commands;

19 (e) an output device, said output device coupled to said processor
20 and providing information comprising external commands, physiological symptoms,
21 wellness parameters, and queries from said communication device, wherein said
22 devices are integrated into a single unit; and

23 a processing computer at a remote central office location in communication
24 with said remote monitoring apparatus for exchanging information with said
25 monitoring apparatus.

1 28. The system according to claim 27 wherein said integrated unit comprises:
2 a base, said base including said physiological parameter transducing device;

3 a housing, said housing including said central processor device, said
4 electronic receiver/transmitter communication device, said input device and said
5 output device; and
6 a support member, said support member having a first end connected to said
7 base and a second end connected to said housing.

1 29. The system according to claim 28, wherein said support member is rigid.

1 30. The system according to claim 28, wherein said support member is
2 adjustable.

1 31. The system according to claim 28, wherein said support member is flexible.

1 32. The system according to claim 27 wherein the physiological parameter
2 transducing device is a scale for monitoring the body weight of a chronic heart
3 failure patient.

1 33. The system according to claim 32 wherein said scale comprises:
2 a top plate defining an interior and exterior surface;
3 a base plate defining an interior and exterior surface;
4 a load cell having a top and bottom side and a first and second end disposed
5 between said top plate and said base plate, wherein the top side of the first end of
6 said load cell is in contact with a first support surface within the interior surface of
7 said top plate, and the bottom side of the second end of said load cell is in contact
8 with a second support surface within the interior surface of said base plate.

1 34. The apparatus according to claim 33 wherein said load cell further comprises
2 a strain gage disposed on said load cell.

1 35. The system according to claim 32 further comprising means for determining
2 whether said patient requires hospitalization or medication adjustments based on
3 said body weight.

1 36. The system according to claim 32 wherein the scale is accurately operable on
2 a hard floor as well as a carpeted floor.

- 1 37. The system according to claim 27 wherein the physiological parameter
2 transducing device is a scale for monitoring the body weight of an overweight or
3 obese individual.
- 1 38. The system according to claim 37 further comprising means for determining
2 whether said individual requires diet modification, or additional nutritional
3 consultation.
- 1 39. The system according to claim 27 further comprising means for determining
2 whether said patient requires hospitalization or medication adjustments based on
3 said wellness parameters.
- 1 40. The system according to claim 27, wherein said communication device is a
2 modem.
- 1 41. The system according to claim 27, wherein said communication is over an
2 RS-232 connection.
- 1 42. The system according to claim 27, wherein said communication device is
2 over an Internet communication device.
- 1 43. The system according to claim 27, wherein said communication device is an
2 infra-red communication device.
- 1 44. The system according to claim 27, wherein said communication device is a
2 power-line carrier communication device.
- 1 45. The system according to claim 27, wherein said communication device is a
2 satellite communication device.
- 1 46. The system according to claim 27, wherein said communication device is a
2 Radio Frequency (RF) transceiver.

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1 47. The system according to claim 46, wherein said RF transceiver has first and
2 second portions, said first portion being operatively coupled to said processor and in
3 radio communication with said second portion, said second portion being located
4 remotely from said first portion and is operatively coupled to said communication
5 network.

1 48. The system according to claim 47, wherein said second portion includes
2 means for wall mounting said second portion.

1 49. The system according to claim 27 wherein a nurse is in communication with
2 said patient through said communication network.

1 50. The system according to claim 27 wherein said output device is a synthetic
2 speech communication device, said speech communication device operatively
3 coupled to said processor and audibly communicating information to said patient.

1 51. The system according to claim 27 wherein said output device is a visual
2 display device.

1 52. The system according to claim 27 wherein said output is a pacemaker
2 coupled to said data input device.

1 53. A method for monitoring an ambulatory patient and establishing
2 communication to a caregiver regarding the wellness parameters of such an
3 ambulatory patient, said method comprising:
4 monitoring a physiological parameters;
5 generating an electronic signal representative of the value of said
6 physiological parameter;
7 in a central processor device, processing said physiological parameter
8 electronic signals;
9 communicating said processed electronic signals between a first location and
10 a remote central location;
11 inputting external commands into said processor; and
12 outputting said information.

- 1 54. The method according to claim 53 wherein the monitoring step includes
2 monitoring the body weight of a chronic heart failure patient.
- 1 55. The method according to claim 54 further comprising determining whether
2 said patient requires hospitalization or medication adjustments based on said body
3 weight.
- 1 56. The method according to claim 53 further comprising determining whether
2 said patient requires hospitalization or medication adjustments based on said
3 wellness parameters.
- 1 57. The method according to claim 53 wherein the communicating step includes
2 communicating to a nurse.
- 1 58. The method according to claim 53 wherein said outputting step includes
2 audibly communicating information to said patient through a synthetic speech
3 communication device.
- 1 59. The method according to claim 53 wherein said outputting step includes
2 visually displaying information.
- 1 60. The method according to claim 49 wherein said outputting step includes
2 inputting data into a pacemaker device.

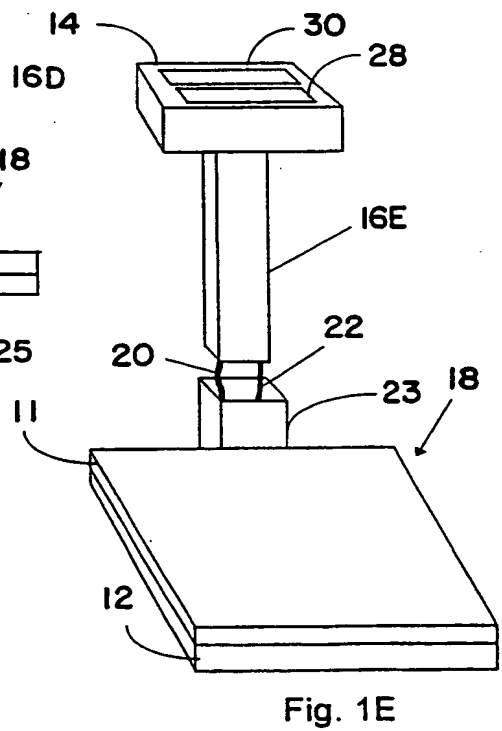
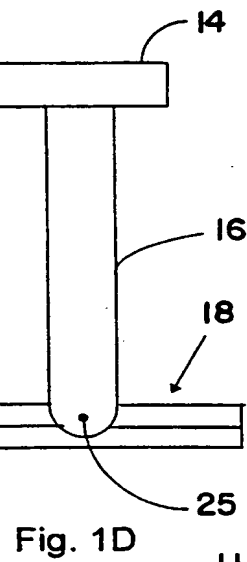
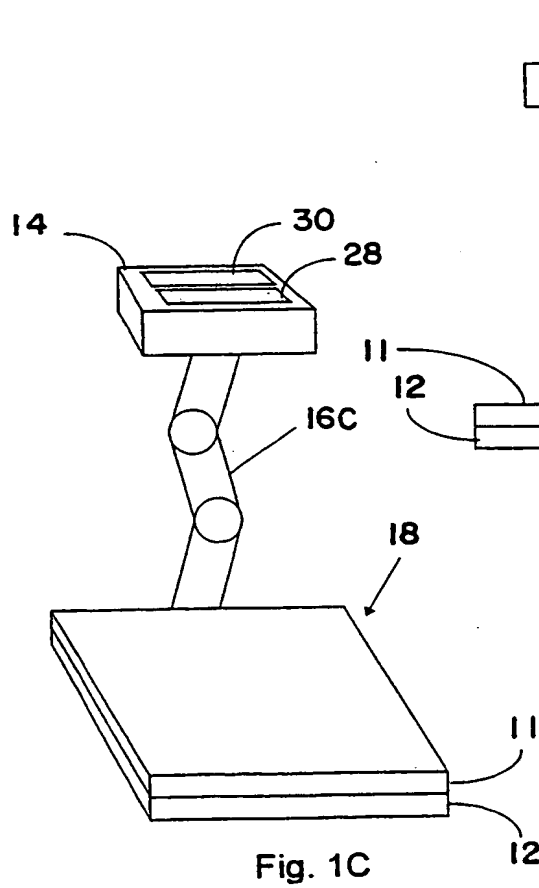
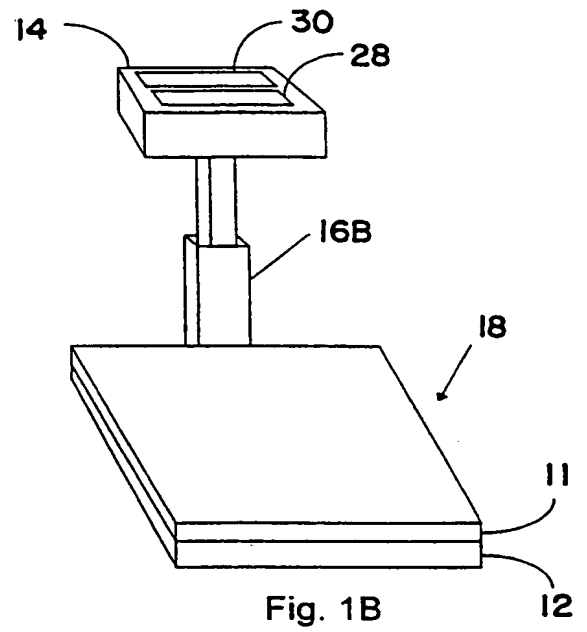
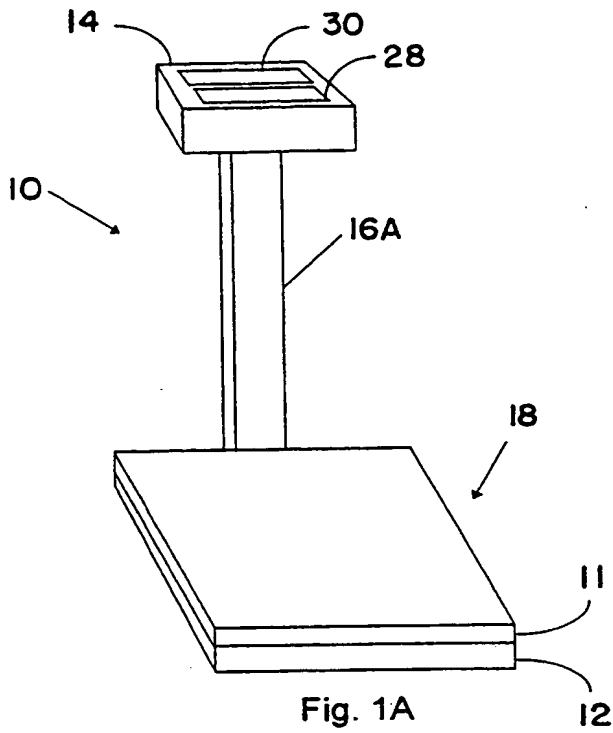
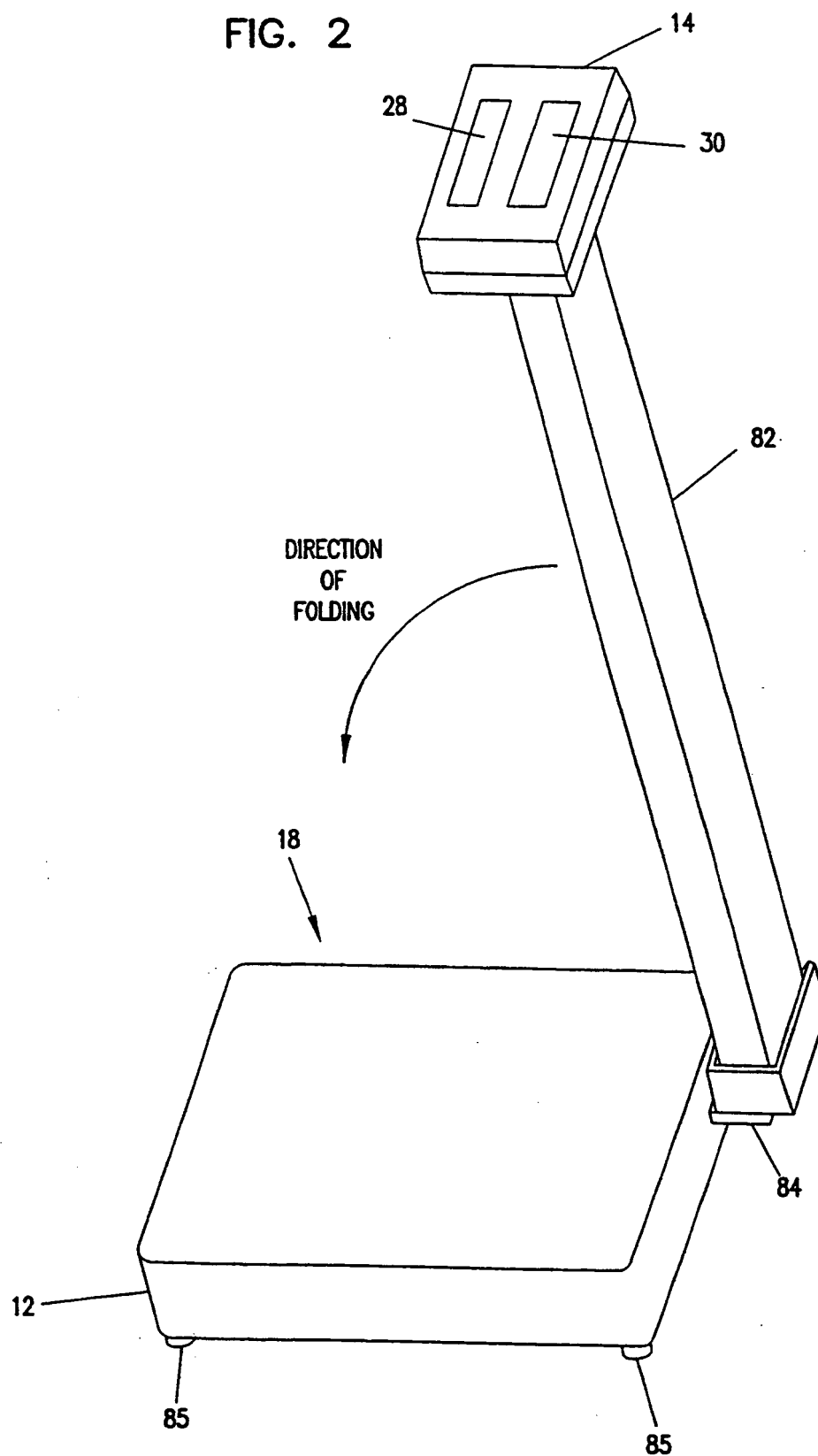
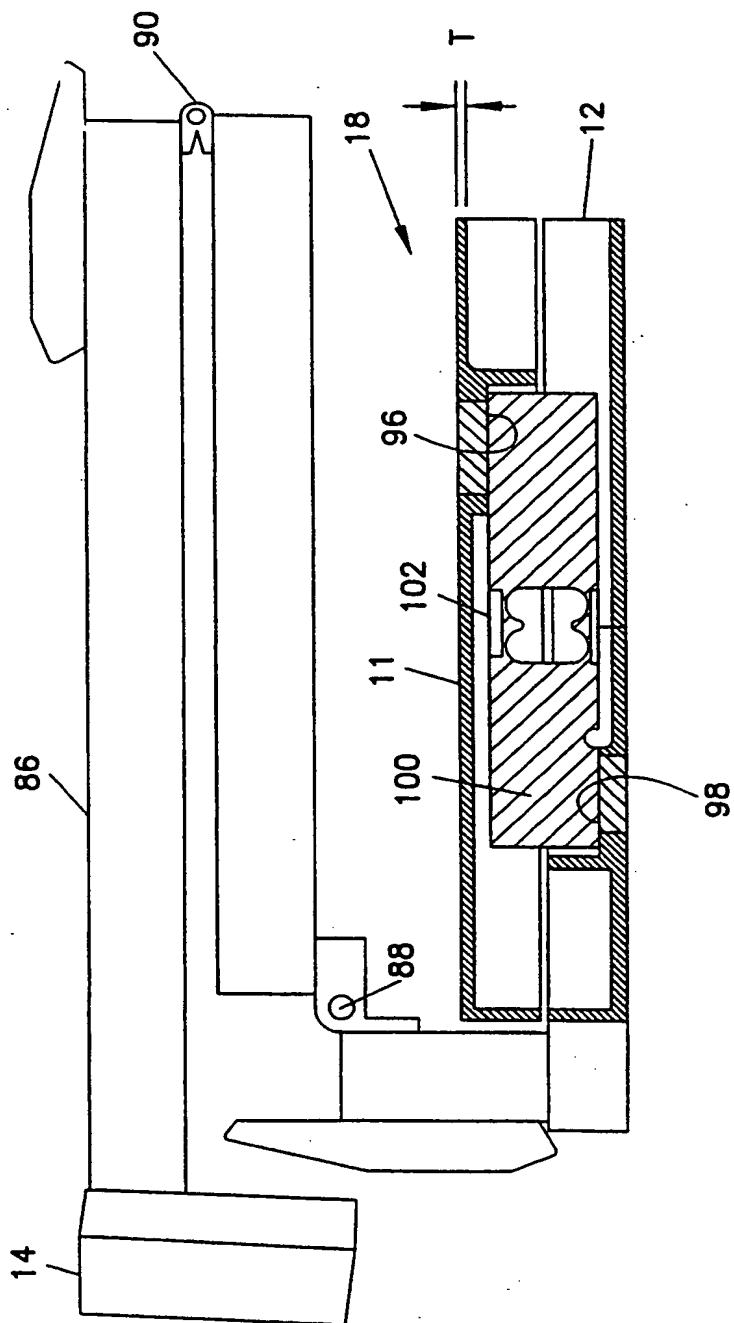


FIG. 2



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FIG. 3



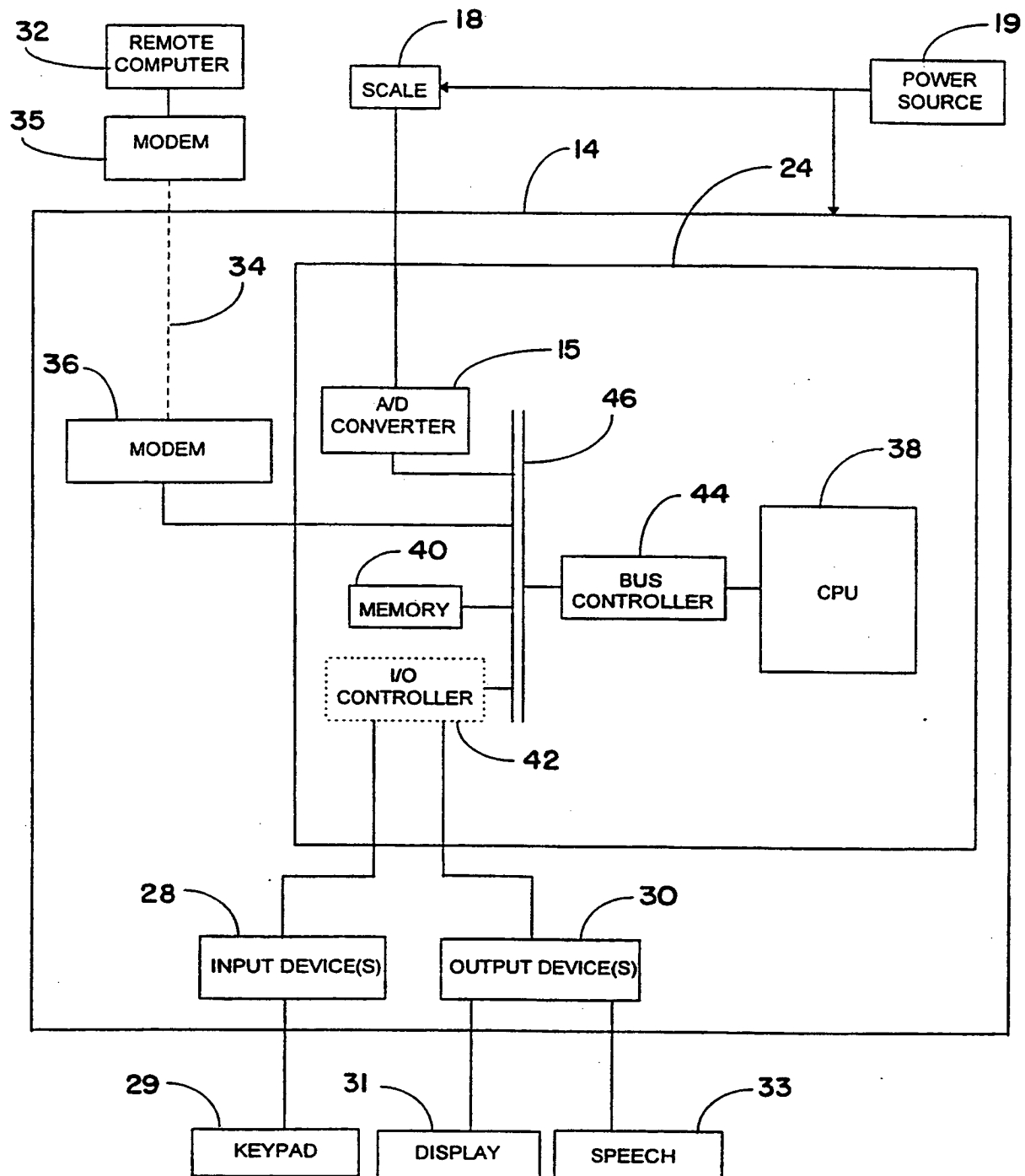
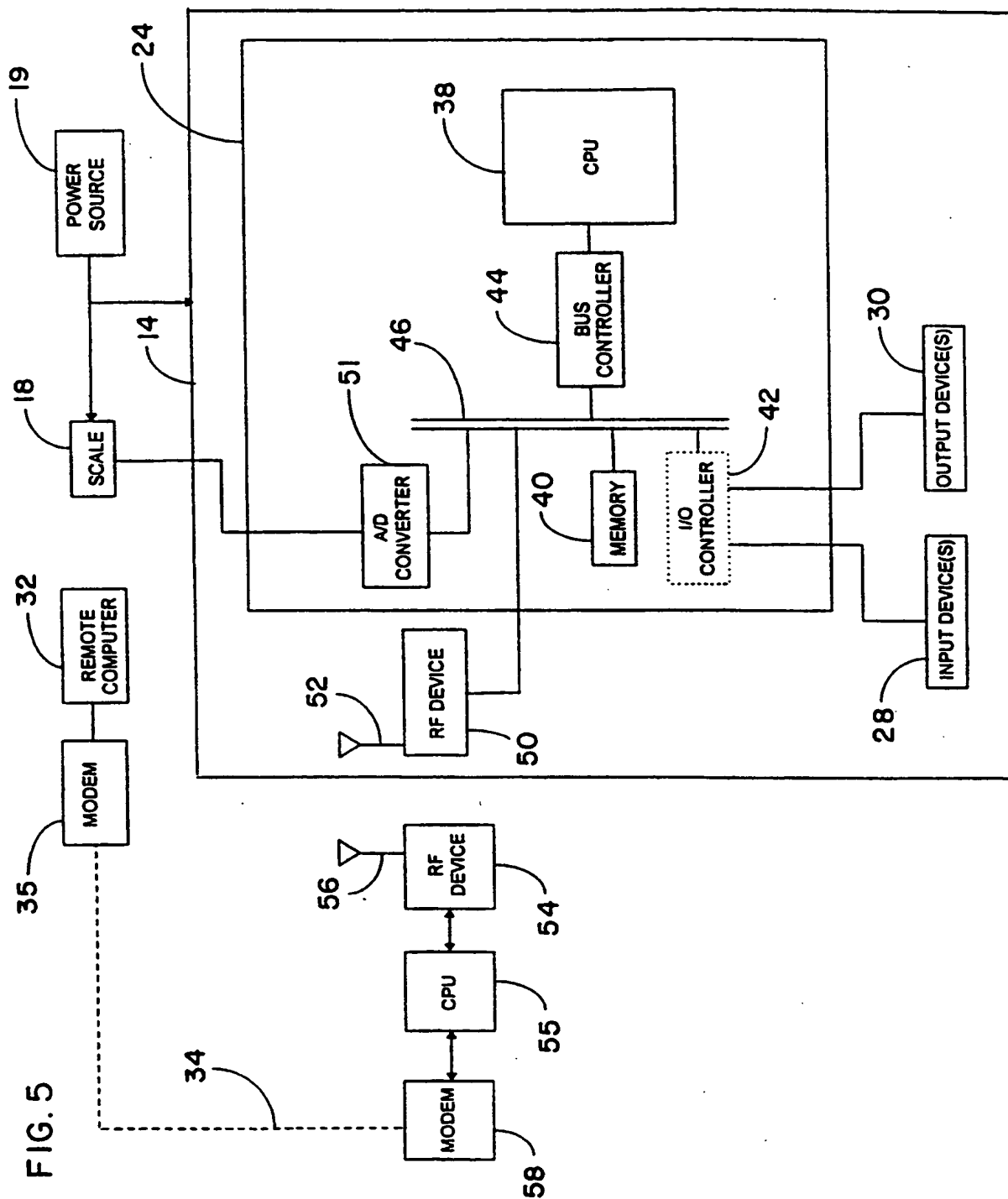


Fig. 4



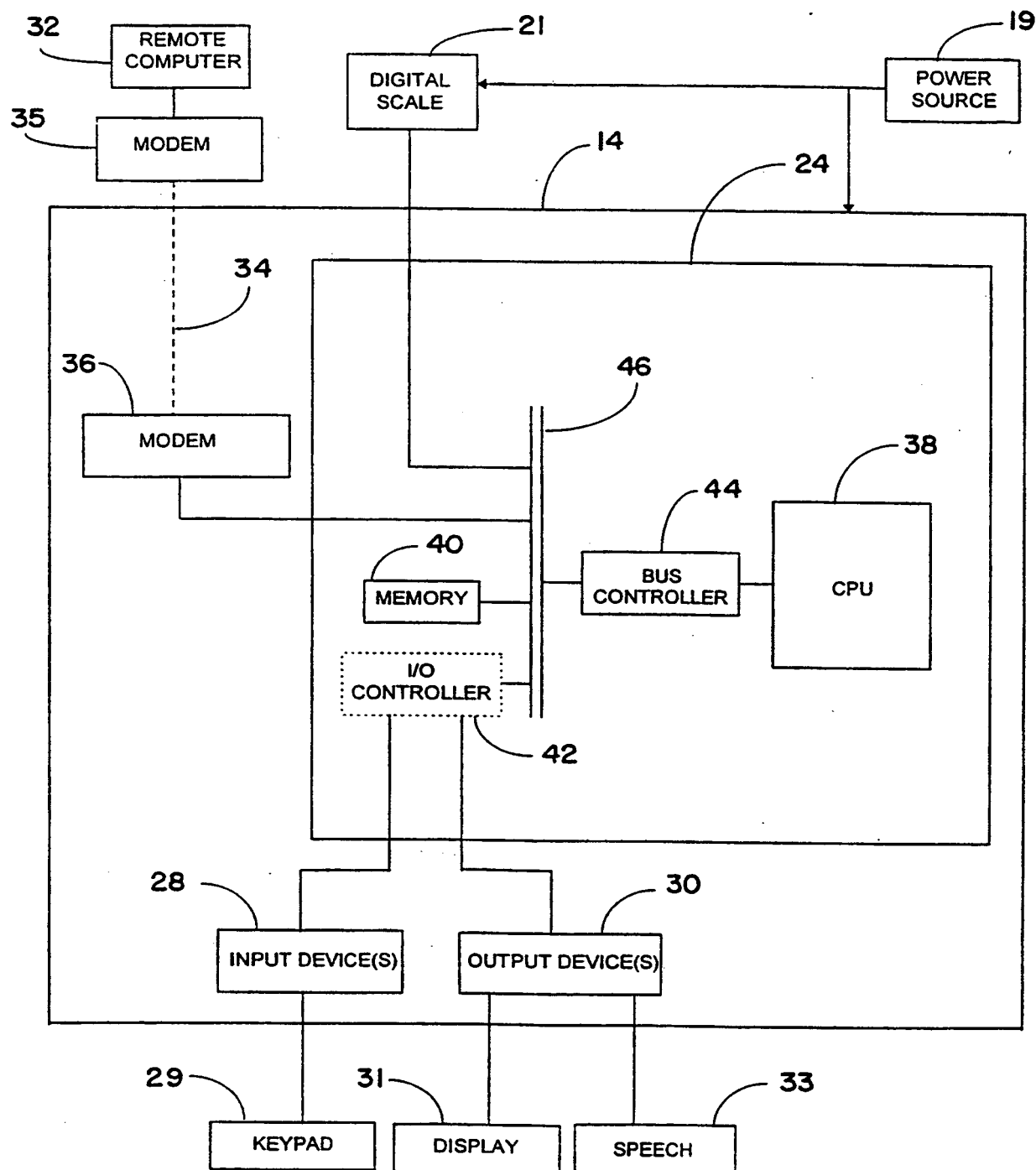


Fig. 6

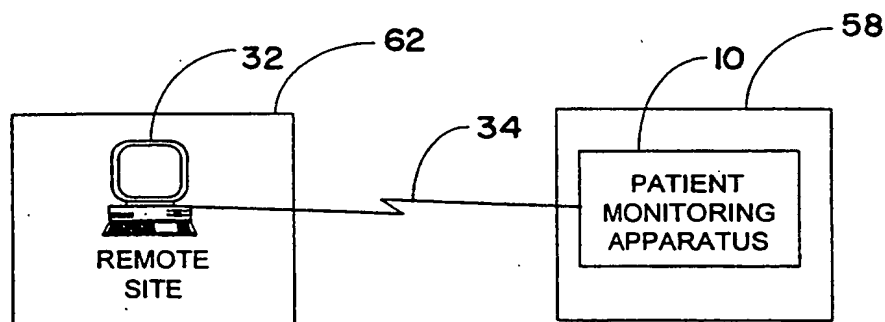


Fig. 7

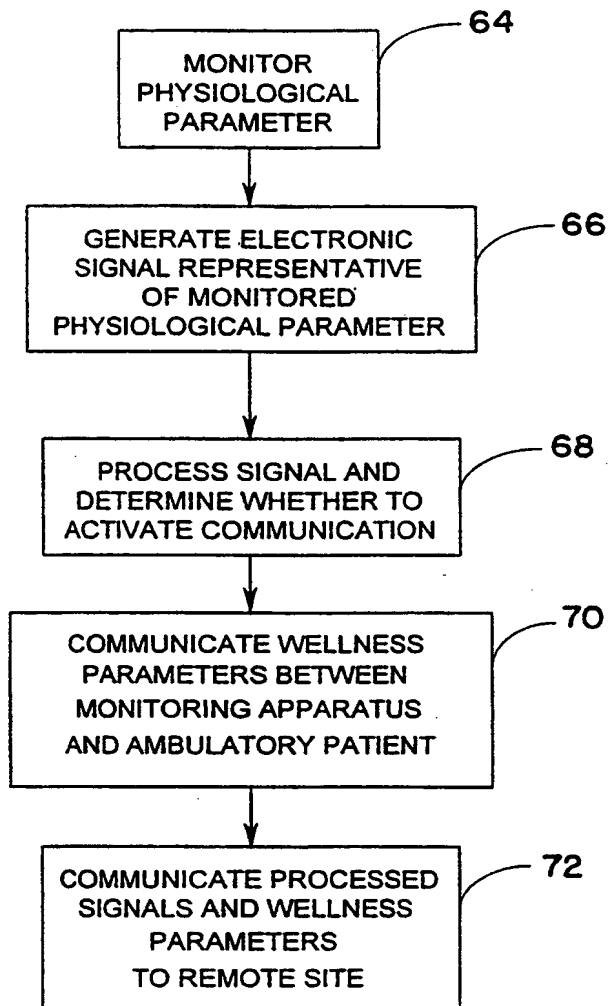
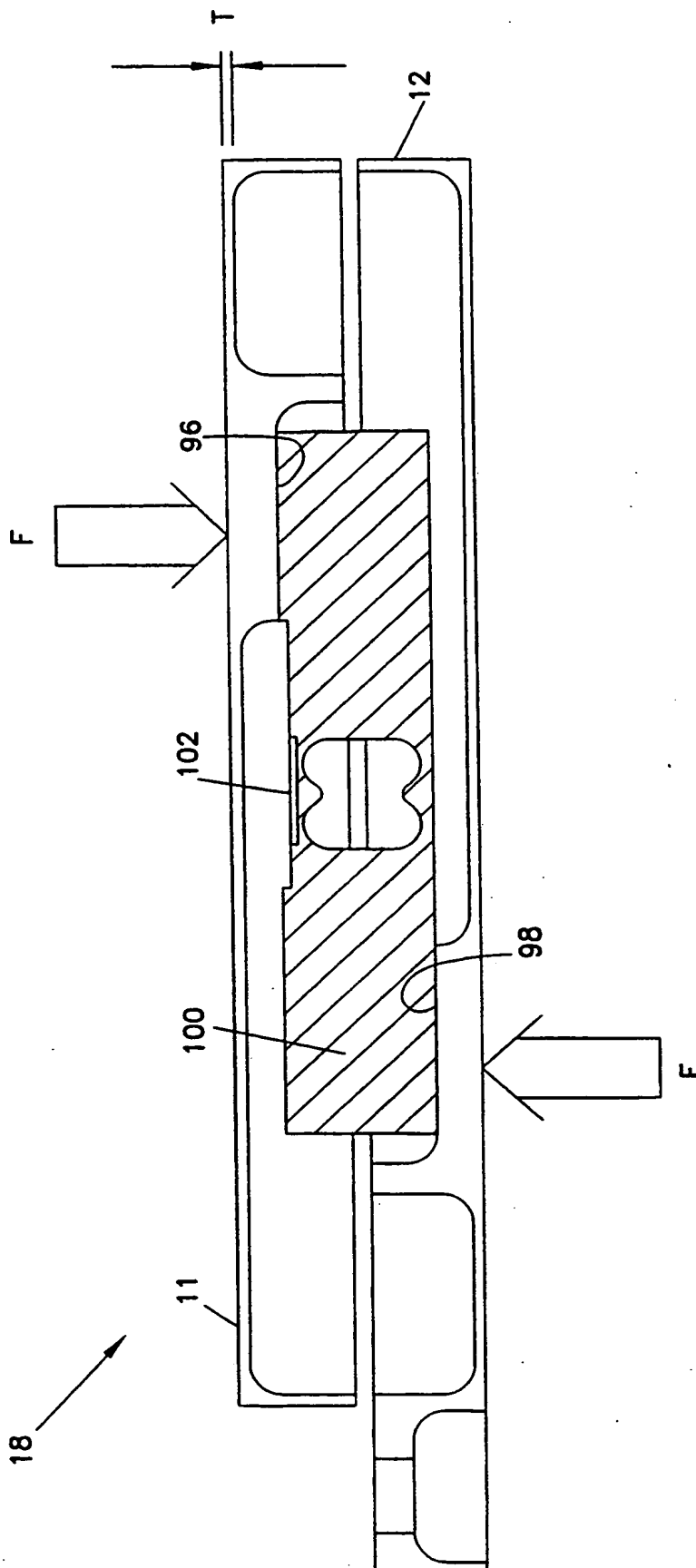


Fig. 8

9 / 10

FIG. 9



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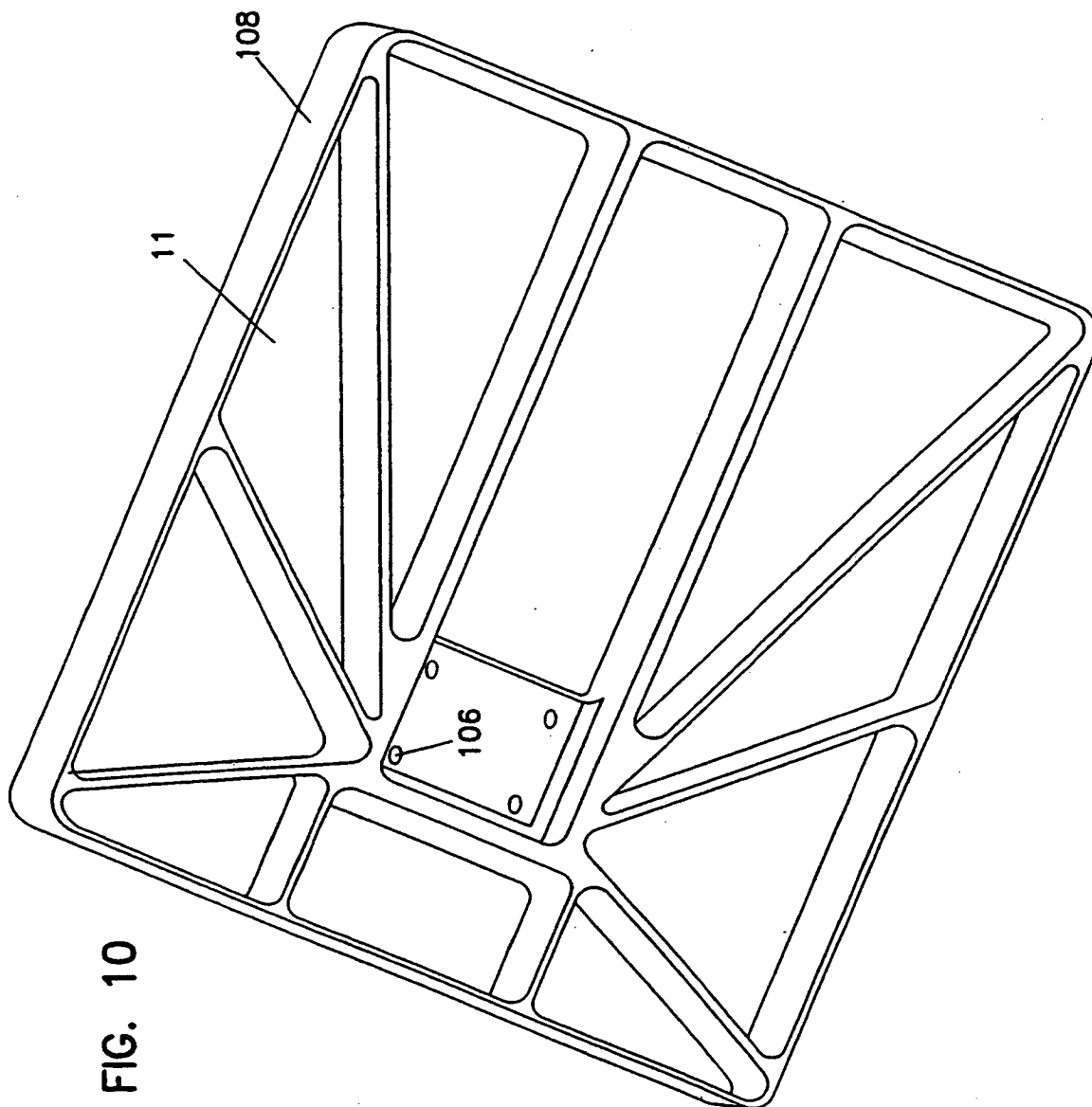


FIG. 10



Published:

— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:
25 January 2001

INTERNATIONAL SEARCH REPORT

Intern. Patent Application No

PCT/US 00/08352

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B5/00 A61N1/372 G08C17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61N G08C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
1 X	PATENT ABSTRACTS OF JAPAN vol. 1997, no. 11, 28 November 1997 (1997-11-28) & JP 09 173304 A (NIPPON DENKI SYST KENSETSU KK;PARAMA TEC:KK; TERADA DENKI SEISAKUSHO:K), 8 July 1997 (1997-07-08) abstract	1,27,53
3 X	US 3 925 762 A (HEITLINGER LOUIS J ET AL) 9 December 1975 (1975-12-09) abstract; figure 1	1,27,53
5 A	DE 43 35 869 A (MAYER WILFRIED) 27 October 1994 (1994-10-27) abstract; figures 1,2	1,27,53

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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- *&* document member of the same patent family

Date of the actual completion of the international search

26 July 2000

Date of mailing of the international search report

30 October 2000 (30.10.00)

Name and mailing address of the ISA

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Authorized officer

Jonsson, P

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/08352

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13,23,39,49,55-57,60
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5,27-31,53

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-5 27-31 53

An apparatus/system/method for monitoring an ambulatory patient and establishing communication to a caregiver regarding the wellness parameters of such an ambulatory patient, comprising: physiological parameter transducers, a CPU, a communication device, input and output units, the devices above being integrated into a single unit, characterised in that the single unit have a support member.

2. Claims: 6-12 32-38 54

All as in 1, except that it is characterised in that the physiological parameter transducer is a scale for monitoring body weight.

3. Claims: 14-22, 40-48

All as in 1, except that it is characterised in the means for communicating the wellness parameters.

4. Claims: 24-26 50-52 58 59

All as in 1, except that it is characterised in the input and output means.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. Appl. Application No

PCT/US 00/08352

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